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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,416	09/28/2001	Erin J. Lindsay	032722-600	2049

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,416

Applicant(s)

LINDSAY, ERIN J.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Priority

1. Applicant indicates that the instant application is a divisional application of 09/244426, filed 2/10/99. For an application to be considered a divisional, it would be filed as a later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application. The divisional application should set forth only that portion of the earlier disclosure that is germane to the invention as claimed in the divisional application. However, no restriction was made and the same invention is claimed in the instant application as was claimed in the parent application. Therefore, since this application discloses and claims only subject matter disclosed in prior Application No. 09/244426, filed 2/10/99, and names an inventor or inventors named in the prior application, this application may constitute a continuation. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. Please advise.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference number **54** is not on figure 1 and reference number **102** is not on figure 2.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 2 is objected to because of the following informalities: The claim recites *at least one "try"* in line 3, which appears to be a grammatical error. It is assumed that applicant intended to recite *at least one tray*. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 12, 20, 21, 30 & 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindsay et al. (5,958,338). Lindsay et al. (hereafter Lindsay) teaches of a mounting apparatus for a blood treatment apparatus and the mounting of the treatment apparatus thereto. The blood treatment apparatus consists of a reservoir (20) and an oxygenator (50), see figure 1. The mounting apparatus allows for releasable mounting of a treatment apparatus and consists of two separate retaining means, or carriers, a

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main apparatus (60) including a slotted plate (90), a retention sleeve (70) which releasably engages slotted plate (90), and a reservoir stem (62). The oxygenator is mounted to said slotted plate by an oxygenator stem (52). The reservoir is mounted to the reservoir stem (52) of the mounting apparatus. Both or one of the reservoir or oxygenator can be removed from their respective mounting apparatus while the other remains attached. (Col. 2 line 9-col. 6, line 26; figures 1-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 8-11, 13, 25-29 & 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay ('338) in view of Fukasawa (4,765,959). Lindsay substantially discloses the invention as claimed, see rejection above, except for the inclusion of various tubing lines, such as a prime line, an A-V loop having an arterial and a venous line, a suction line attached to the reservoir, a pump and pump loop, and wherein all of these items are part of the pack assembly prior to use. Lindsay also does not teach the inclusion of a flexible venous reservoir mounted on the carrier.

Fukasawa teaches a blood circulation circuit that has support structures, said circuit comprising two reservoirs (32,44) wherein one is a flexible reservoir, a pump and pump (43) lines, suction line (42), an oxygenator (35), a venous blood line (36), a blood

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circulating and a return lines (31,40), a stand (39) for holding the reservoir by means of a hook (45), and an enclosure (33) structure for holding the reservoir (32). The system is put together prior to connection to a patient and use of the system.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the system of Lindsay to include the tubing lines, a flexible venous reservoir, and a pump in order for proper blood treatment when using the apparatus. Since Lindsay teaches that the blood handling apparatus "may be any apparatuses commonly employed in an extracorporeal circuit," it is reasonable to modify the system to include the above elements since they are well known in the art to be used in extracorporeal blood circuits, to provide a complete system for proper blood treatment. Also, it would have been obvious for the items to be mounted within the pack assembly for ease of transportation since they are all well known to be required components for blood treatment systems.

6. Claims 1, 4, 12, 16, 18, 20, 29, 30 & 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBride (5,800,721) in view of Fukasawa (4,765,959).

McBride discloses a combined cardiectomy and venous blood reservoir (10) having a support member (i.e. carrier) made up of a basin (50) including elements to attach the reservoir to an oxygenator (not shown). The support member has brackets (44) that attach to fingers (54) on the bottom of the reservoir. The bottom portion of the basin has hooks (46) that attach the reservoir and oxygenator in a releasable manner. See col. 6, line 50-col. 7, line 45; figures 2 & 4.

McBride substantially discloses the invention as claimed, except for the inclusion of various tubing lines, such as a prime line, an A-V loop having an arterial and a venous line, a suction line attached to the reservoir, a pump and pump loop, and wherein all of these items are part of the pack assembly prior to use. McBride also does not teach the inclusion of a flexible venous reservoir mounted on the carrier. Fukasawa teaches a blood circulation circuit that has support structures, said circuit comprising two reservoirs (32,44) wherein one is a flexible reservoir, a pump and pump (43) lines, suction line (42), an oxygenator (35), a venous blood line (36), a blood circulating and a return lines (31,40), a stand (39) for holding the reservoir by means of a hook (45), and an enclosure (33) structure for holding the reservoir (32). The system is put together prior to connection to a patient and use of the system.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the system of McBride to include the tubing lines, a flexible venous reservoir, and a pump in order for proper blood treatment when using the apparatus. Since McBride teaches that the blood handling apparatus is for use in surgical procedures, it is reasonable to modify the system to include the above elements since they are well known in the art to be used in extracorporeal blood circuits, to provide a complete system for proper blood treatment. Also, it would have been obvious for the items to be mounted within the pack assembly for ease of transportation since they are all well known to be required components for blood treatment systems.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 2-11 & 29-31 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. **6,306,346**. This is a double patenting rejection.

Application claim 2 is identical to patent '346 claim 1
Application claim 3 is identical to patent '346 claim 2
Application claim 4 is identical to patent '346 claim 3
Application claim 5 is identical to patent '346 claim 4
Application claim 6 is identical to patent '346 claim 5
Application claim 7 is identical to patent '346 claim 6
Application claim 8 is identical to patent '346 claim 7
Application claim 9 is identical to patent '346 claim 8
Application claim 10 is identical to patent '346 claim 9
Application claim 11 is identical to patent '346 claim 10
Application claim 29 is identical to patent '346 claim 11
Application claim 30 is identical to patent '346 claim 12
Application claim 31 is identical to patent '346 claim 13

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8. Claim 12 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 12/1 of prior U.S. Patent No. **6,306,346**. This is a double patenting rejection.

Application claim 12 is identical to patent '346 claim 12/1.

The application claim 12 includes all of the limitations of patent claim 12, which inherently includes all the limitations of patent claim 1.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. **6,306,346**.

With respect to claim 1, although the conflicting claims are not identical, they are not patentably distinct from each other because application claim 1 is a broader recitation of the invention than that of the issued claim 1 of patent '346, including all of the same limitations. The claims of the application claim a pack assembly comprising parts (a), (b) and (c) as recited in the parent claim. The patent claims recite an

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additional recitation, part (d), setting forth the pack assembly including at least one tray releasably attached to at least one of the carrier, oxygenator, or reservoir. Since a broad interpretation of patent claim 1 inherently includes the invention of the pack assembly having parts (a)-(c) as claimed in claim 1 of the application, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '346 patent.

10. Claims 13-18, 20, and 22-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10 & 13 of U.S. Patent No. **6,306,346**.

As noted above with respect to the rejection of independent claim 12 under 101 Double Patenting, although the conflicting claims are not identical, they are not patentably distinct from each other because application claim 12 is an obvious recitation of the invention than that of the issued claim 1 of patent '346, including all of the same limitations. With respect to claims 13-18, 20 & 22-28, all are dependent from application claim 13. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to modify application claim 12 to include the limitations as set forth in patent claims 2-10 & 13, and if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '346 patent.

11. Claims 19 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12/1 & 3 of U.S. Patent No. **6,306,346** in view of **5,958,338**.

Patent No. **6,306,346** substantially claims the invention, however, does not claim wherein the mounting bracket includes a slotted track and wherein the blood oxygenator includes an attachment disk projecting from its surface on a stem and the lower surface of the mounting element has a channel for slidably engaging and releasing the attachment disk. Patent **5,958,338** discloses a blood treatment apparatus consists of a reservoir (20) and an oxygenator (50), further including a mounting apparatus that allows for releasable mounting of a treatment apparatus, including a slotted plate (90), or attachment disk, and wherein the oxygenator is mounted to said slotted plate by an oxygenator stem (52). The attachment is slidable. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to modify application claim 12 to include the limitations as set forth in patent **5,958,338**, and if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '346 patent.

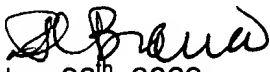
Conclusion

12. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb 
October 30th, 2003